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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:

COX et al.

Serial No.: 09/889,273

Filed: July 13, 2001

Atty. File No.: 4152-2-PUS

For: "METHODS FOR MAKING
PROTEINS CONTAINING FREE
CYSTEINE RESIDUES"

) Group Art Unit: 1647

) Examiner: Hamud, Fozia M.

) RESPONSE TO
) RESTRICTION REQUIREMENT

) EXPRESS MAIL: EV331285354US

RECEIVED

MAY 28 2003

TECH CENTER 1600/2900

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This response is filed in response to a Restriction Requirement having a mailing date of April 28, 2003. This response is believed to be timely and therefore, no fees are enclosed. In the event that fees are due in connection with this response, please debit Deposit Account No. 19-1970.

The Examiner has restricted the present application into five groups of claims, as follows: Group I (Claims 1-25 and 29-31), directed to a method of producing a soluble protein and a composition comprising a soluble protein and polyethylene glycol; Group II (Claim 26), directed to a composition comprising at least two proteins, attached through a free cysteine; Group III (Claims 27-28), directed to a method of treating a condition by administering a pegylated form of growth hormone; Group IV (Claims 27-28), directed to a method of treating a condition by administering a pegylated form of erythropoietin; and Group V (Claims 27-28), directed to a method of treating a condition by administering a pegylated form of alpha interferon. Applicants provisionally elect with traverse to prosecute Group I (Claims 1-25 and 29-31).

Applicants traverse the restriction between Groups I and II-V. As the Examiner notes in the Office Action, since this is a national stage application, the regulations of 37 CFR 1.475(d) apply. According to MPEP 1893.03(d), a group of inventions is considered to be linked to form a single

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general inventive concept when there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. A process is "specially adapted" for the manufacture of a product if the claimed process inherently produces the claimed product with the technical relationship being present between the claimed process and product.

With regard to Groups I and II, in this case, the Examiner asserts that the claims of Groups I and II differ in that the product of Group II is a materially and functionally dissimilar product that does not correspond to the main invention. The Examiner states that the main invention is a method of producing a soluble protein and the first-recited product produced in said method. In traverse of the division between Groups I and II, Applicants submit that Groups I and II are linked by the corresponding special technical feature of producing a soluble protein *having a free cysteine*, which should include the products having free cysteines produced thereby, as well as methods that make use of the free cysteine (e.g., by further modification or dimerization of proteins). In the case of the first recited products in Group I and the product recited in the claim of Group II, the proteins, whether monomeric or multimeric, the products are all soluble proteins having a free cysteine that can be produced by the method claims of Group I, whether or not the proteins are then further modified by cysteine reactive moieties or multimerization. Therefore, it is submitted that the groups are capable of being examined together, and there would be no undue burden on the Examiner to rejoin the groups for examination.

With regard to the combination of Group I and Groups III-IV, Groups III-IV represent a process of using the protein of Group I. According to 37 CFR 1.141 and MPEP806.05(i), where claims to all three categories (product, process of making and process of using) are included in a national application, the process of using can be joined with the product and process of making, even if distinctness can be shown between the product and the process of using. In any event, if the elected claims of Group I are found allowable, Applicants reserve their right to amend the claims of Groups III-V to be commensurate in scope with the product claims of Group I, and to request that such amended method that depend from or otherwise include all the limitations of the allowable

product be rejoined and examined for patentability. In re Brouwer, 37 USPQ2d 1663 (Fed. Cir. 1996); In re Ochiai, 37 USPQ2d 1127 (Fed. Cir. 1995).

Respectfully submitted,

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